

Exhibit B

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC.) Master File No.
5 PELVIC REPAIR SYSTEM) 2:12-MD-02327
6 PRODUCTS LIABILITY)
7 LITIGATION) MDL No. 2327
8 _____)

9 THIS DOCUMENT RELATES TO) JOSEPH R.
10 PLAINTIFFS:) GOODWIN
11) U.S. DISTRICT
12 Mary Hendrix) JUDGE

13 Case No. 2:12-cv-00595)

14 Danni Laffoon)

15 Case No. 2:12-cv-00485)

16 Alfreda Lee)

17 Case No. 2:12-cv-01013)

18 Mary Holzerland)

19 Case No. 2:12-cv-00875)

20 Heather Long)

21 Case No. 2:12-cv-01275)

22 Donna Shepherd)

23 Case No. 2:12-cv-00967)

24 Cheryl Lankston)

 Case No. 2:12-cv-00755)

DEPOSITION OF

CHRISTOPHER E. RAMSEY, M.D.

Taken on behalf of the Plaintiff

April 6, 2016

6:11 p.m.

1 said earlier ten proctor- -- ten observations and
2 then maybe ten proctorships.

3 Q. How many times total do you think
4 Ethicon paid you for an event?

5 A. Like I said, 15 to 20 times, probably.

6 Q. Did you ever serve on any advisory
7 boards for Ethicon?

8 A. No. Not --

9 Q. No?

10 A. No.

11 Q. Ethicon ever ask you to serve on any
12 advisory boards?

13 A. No.

14 Q. Ever serve on any product review
15 committees --

16 A. No.

17 Q. -- for Ethicon?

18 A. No committees, no.

19 Q. Ethicon ever ask you to serve on any
20 product review committees?

21 A. No.

22 Q. Ever serve on any product design
23 committees for Ethicon?

24 A. No.

1 Q. Ever serve on any IFU committees for
2 Ethicon?

3 A. No.

4 Q. Ethicon ever ask you to serve on any
5 IFU committees?

6 A. No.

7 MR. MORIARTY: Objection.

8 Go ahead.

9 BY MR. JONES:

10 Q. Ethicon ever ask you to serve on any
11 product design committees?

12 MR. MORIARTY: Objection.

13 Go ahead.

14 THE WITNESS: No.

15 BY MR. JONES:

16 Q. Sounds like -- is it fair to say for a
17 six-year period you were a consultant physician for
18 Ethicon?

19 A. Yes.

20 Q. And during that six-year period,
21 Ethicon never approached you to serve on any
22 advisory boards or product review committees,
23 correct?

24 MR. MORIARTY: Objection.

1 THE WITNESS: Right, correct.

2 BY MR. JONES:

3 Q. Did they ever ask you -- did Ethicon
4 ever ask you to provide input into drafting any
5 IFUs?

6 A. No.

7 Q. Did Ethicon ever ask you to provide any
8 input into assisting with any department at Ethicon
9 in drafting IFUs?

10 A. No.

11 Q. Did Ethicon ever ask you to help design
12 any of their mesh products?

13 A. No.

14 Q. Ethicon ever ask you to do a
15 risk/benefit analysis on any of their mesh
16 products?

17 A. No.

18 Q. When did you first become certified in
19 urology, board certified?

20 A. Board certified in 2004, is when my
21 board certification took place.

22 Q. When is the first time you put in a
23 transvaginal mesh product?

24 A. Probably around 2000, in residency.

1 and TVT Retropubic. I probably did -- I didn't do
2 very many TVT Retropubics total, including in
3 residency and private practice. So between 25 to
4 50 Retropubics ever. And I haven't done one of
5 those in several -- years.

6 Q. Okay. We'll get to that later.

7 A. Okay.

8 Q. At 2000- -- in 2005, you had implanted
9 around 100 TVT mesh products, correct?

10 A. Correct.

11 Q. In 2005, Ethicon approached you to be a
12 consultant physician for them, correct?

13 A. Right.

14 Q. So a year after you became board
15 certified in urology, you were a consultant
16 physician for Ethicon related to transvaginal mesh
17 products, correct?

18 A. Repeat the question again.

19 Q. One year following -- a year after you
20 became board certified in urology, you signed a
21 contract to be a consultant physician for Ethicon
22 related to transvaginal mesh products?

23 A. Probably.

24 Q. What percentage of your practice is

1 relating to treating males?

2 A. Now it's probably 70 percent.

3 Q. Currently 70 percent of your practice
4 relates to treating males?

5 A. Yes.

6 Q. Do you know whether you're one of the
7 most prolific users of the da Vinci robot system in
8 the United States or not?

9 A. I think I am.

10 Q. What procedures do you use the da Vinci
11 robot system for?

12 A. Prostatectomy, nephrectomy, partial
13 nephrectomy, nephroureterectomy, pyeloplasty,
14 ureteral reimplantation.

15 Q. Do any of those procedures relate to
16 the treatment of females?

17 A. Yes.

18 Q. Which ones?

19 A. Pyeloplasty, nephrectomy, partial
20 nephrectomy, nephroureterectomy, reimplantation,
21 fistula.

22 Q. Any of those relate to treating stress
23 urinary incontinence?

24 A. No.

1 A. Yes. That's correct.

2 Q. Are you going to be offering opinions
3 in this litigation as to the safety of the TVT
4 Exact?

5 A. Not that I know of.

6 Q. Okay. How about TVT Abbrevio?

7 A. Not that I know of.

8 Q. How about TVT-Secur?

9 A. Yes.

10 Q. TVT-R?

11 A. Yes.

12 Q. TVT-O?

13 A. Yes.

14 MR. JONES: All right. Exhibit 3.

15 (Whereupon Exhibit 3 was marked as an
16 exhibit.)

17 BY MR. JONES:

18 Q. Take a look at that. Tell us what
19 Exhibit 3 is.

20 A. This is my reliance list. And it's
21 specifically for Cheryl Lankston, but I think it's
22 basically the reliance list I've used for all my
23 reports.

24 Q. Okay. And did you draft this reliance

1 list?

2 A. I assisted with the drafting of this
3 list.

4 Q. Okay. How did you assist in drafting
5 this list?

6 A. The -- the Ethicon lawyers helped me
7 with -- with some -- some of this.

8 Q. Okay. What is your understanding of
9 what's included in the reliance list --

10 A. These are --

11 Q. -- marked as Exhibit 3?

12 A. These are studies and documents that I
13 used to make my list -- I'm sorry -- make my expert
14 reports.

15 Q. How long did you spend reviewing the
16 materials listed in your reliance list?

17 A. Oh, gosh. I continue to do it,
18 continue to review them. But probably 30 or 40
19 hours.

20 Q. You're continuing to review those
21 materials, correct?

22 A. Yes.

23 Q. So, as of today, you have not reviewed
24 every single one of the materials listed in your

1 reliance list, correct?

2 A. I have reviewed all of them. I may not
3 have read every single word in every one of them,
4 but I've reviewed them and looked at them.

5 Q. Every single one of the items listed on
6 your reliance list --

7 A. To the best of my knowledge.

8 Q. -- marked as Exhibit 3, you have
9 actually taken a look at and reviewed, correct?

10 A. To the best of my knowledge.

11 Q. Okay. And if it's not listed -- if an
12 item is not listed on Exhibit 3, your reliance
13 list, then it's an item that you have not reviewed
14 in preparation for your report and your opinions in
15 this case, correct?

16 A. I probably have reviewed other things
17 that are not on this list that -- that I have
18 reviewed.

19 Q. Okay.

20 A. I cannot tell you the exact documents
21 that I may have looked at.

22 You know, for sure I've looked at
23 Campbell's "Urology," other well-known -- excuse
24 me -- books and volumes on urology.

1 A. No.

2 Q. Do you know who Catherine Beath is?

3 A. No.

4 Q. Do you know who Ming Chin is?

5 A. No.

6 Q. Do you know who Martin Weisberg is?

7 A. No.

8 Q. Do you know who Laura Angelini is?

9 A. No.

10 Q. Do you know who Aaron Kirkemo is?

11 A. No.

12 Q. Can you name a single medical director
13 at Ethicon?

14 A. No.

15 Q. Can you name a single TVT design
16 engineer at Ethicon?

17 A. I guess you can call Dr. Ulmsten a
18 design engineer.

19 Q. Do you know who Dan Lamont is?

20 A. No.

21 Q. Do you know who Dan Smith is?

22 A. No.

23 Q. Do you know who designed the TVT-Secur?

24 A. No.

1 BY MR. JONES:

2 Q. Complication rates?

3 A. Complication, yes.

4 Q. You will be offering opinions in this
5 litigation related to the complication rates of the
6 TVT products, correct?

7 A. Yes.

8 Q. The materials on your reliance list,
9 did Ethicon provide you these materials?

10 A. They helped me with -- with this.
11 There are some that are known fairly well, but --
12 but, yes, I did have help.

13 Q. Okay. How did you get the internal
14 documents?

15 A. Oh, Ethicon gave me the internal
16 documents.

17 Q. How did you get the medical literature?

18 A. Oh, from -- the medical literature?

19 Q. Yes.

20 A. Those are published in our medical
21 journals.

22 Q. How did you get them?

23 A. By reading the journals, by going to
24 conferences.

1 Q. Okay. Turn to page -- so you actually
2 went and retrieved these articles listed in the
3 medical --

4 A. So -- most of these were given to me,
5 but I --

6 Q. Most of these were given to you by
7 Ethicon?

8 A. -- but I knew what they -- I knew what
9 a lot of them are.

10 Q. That's what I'm getting at --

11 A. Right.

12 Q. -- is how you actually physically got
13 these.

14 A. Oh, they were given to me.

15 Q. Ethicon physically gave you these
16 documents?

17 A. Well, my lawyers did.

18 Q. Ethicon's lawyers physically gave you
19 these documents?

20 A. Yes.

21 Q. And they're the ones who decided which
22 articles to give you, correct?

23 A. Not all of them, no.

24 Q. Sometimes you asked for some articles?

1 A. Yes.

2 Q. Which ones?

3 A. Gosh, I can't --

4 Q. As you sit here today, you can't name a
5 single article?

6 A. I can't -- I can't name a single
7 article that I asked for specifically.

8 Q. How about -- turn to the first page.

9 A. Uh-huh.

10 Q. I'll pick one out for you. This
11 Abdel-Fattah, "Single-Incision Mini-Slings Versus
12 Standard Midurethral Slings in Surgical Management
13 of Female SUI: A Meta-analysis of Effectiveness
14 and Complications," in "European Urology."

15 Do you see that listed on page 1?

16 A. Which one -- which one is that one?

17 Q. I just read it.

18 A. Yeah. Which one down the list? One,
19 two, three, four, five -- five?

20 Q. Yeah.

21 A. Yeah. That's one that I've seen in
22 some -- in the conferences in the past. I can't
23 remember when.

24 Q. Okay.

1 Q. Which physicians refer patients to you
2 to treat mesh complications?

3 A. I honestly don't know. I've not had
4 anybody refer their own complications to me.

5 Q. Okay.

6 A. I've had maybe -- a couple GYNs refer
7 patients of theirs that they noticed had mesh
8 complications to me, but I don't -- I don't recall
9 the specific physicians.

10 Q. And those surgeons currently are
11 referring you patients specifically to treat mesh
12 complications, correct?

13 A. Well, not specific -- that's part of
14 what they refer, that -- they're just -- the
15 physicians refer to me most of their patients
16 anyway for whatever GYN issue that they want me to
17 treat.

18 So if they have a patient that comes to
19 see them and they may have had a mesh put in by
20 somebody else, a sling put in by somebody else, and
21 there's an issue, then they'll send them to me.

22 Q. Okay.

23 A. Doesn't happen very often.

24 Q. Doesn't happen very often?

1 A. No. Women. Specifically women. I'm
2 sorry. There are men with stress incontinence I
3 deal with, but --

4 Q. But never over half, correct?

5 A. Never over half of my practice being
6 female stress incontinence? No.

7 Q. Not a single year as -- that you've
8 been a practicing urologist has over half of your
9 practice related to treating women with stress
10 urinary incontinence, correct?

11 A. That's correct.

12 Q. Do you hold yourself out in any regard
13 in the medical community as an expert in treating
14 mesh complications?

15 A. I don't try to advertise myself as a
16 doctor who treats mesh complications. I would say
17 that I'm an expert at treating mesh complications.

18 Q. Have you referred patients suffering
19 from mesh complications to any other surgeons?

20 A. Yes.

21 Q. Who?

22 A. I usually send them to Vanderbilt.

23 Q. Who at Vanderbilt?

24 A. Dr. Demkowski, and I'm not certain --

1 Surgeons."

2 Q. Anything else?

3 A. No other journals, no.

4 Q. Okay. Gold journal and "Journal of
5 Urology" are the only two journals you subscribe to
6 that might relate to stress urinary incontinence
7 and transvaginal mesh, correct?

8 A. Correct.

9 Q. How often do you do an independent
10 literature search on the products you use in your
11 practice?

12 A. Usually when I first start to use the
13 product, and then intermittently afterwards,
14 depending on, you know, if I see something new in a
15 conference that may pertain to that device, then
16 I'll look into that as well.

17 Q. Okay. It's your practice as a
18 physician, prior to using a product, you perform an
19 independent literature search on that product,
20 correct?

21 A. Yes.

22 Q. And I take it you don't just rely on
23 the representations of that company's sales rep?

24 A. No, no.

1 Go ahead.

2 THE WITNESS: No, I haven't seen any --
3 any type of long-term study that has suggested that
4 a softer mesh may have a better result or decrease
5 the inflammation compared to what's already been
6 shown to have very good efficacy.

7 BY MR. JONES:

8 Q. Have you seen any medical literature
9 that discusses whether stiff mesh may be
10 potentially detrimental to the woman's adjacent
11 tissues to the mesh?

12 MR. MORIARTY: Objection to form.

13 Go ahead.

14 THE WITNESS: No, I have not.

15 BY MR. JONES:

16 Q. You haven't reviewed any medical
17 literature that discusses the stiffness values of
18 transvaginal mesh and that relationship to
19 complications in women?

20 A. I haven't seen anything like that.

21 Q. Okay. Do you know who Pam Moalli is?

22 A. I have seen Moalli's studies.

23 Q. Okay. And generally speaking, what is
24 the discussion involved in the Moalli studies?

1 A. No.

2 Q. Have you been ever asked to participate
3 in a clinical trial for the treatment of female SUI
4 with transvaginal mesh?

5 A. No.

6 Q. Ethicon's never asked you to
7 participate in a study like that?

8 A. No.

9 Q. AMS never asked you to participate in a
10 study like that?

11 A. No.

12 Q. Have you ever published -- how about
13 this: Have you ever done any studies focusing on
14 treating pelvic pain in women?

15 A. No.

16 Q. Ever studied treating dyspareunia in
17 women?

18 A. Have I studied it?

19 Q. Yeah.

20 A. Or have I done a study?

21 Q. Have you done a study?

22 A. No.

23 Q. Published any literature on dyspareunia
24 in women?

1 A. No.

2 Q. Published any articles whatsoever on
3 women's SUI?

4 A. No.

5 Q. Using mesh in women -- published
6 anything on using mesh in women?

7 A. No.

8 Q. How about on -- have you done any
9 research on graft materials --

10 A. I've --

11 Q. -- of treatment of SUI in women?

12 A. I've researched it.

13 Q. Okay. And what was the just findings
14 of your research?

15 A. Again, not clinical research -- not --
16 not bench science research, but just clinical
17 research of the medical literature.

18 Q. Okay.

19 A. So I've not --

20 Q. You've never done a study --

21 A. Correct.

22 Q. -- on the Burch procedure, correct?

23 A. No.

24 Q. Never done a study on any graft

1 material, correct?

2 A. Correct.

3 Q. Never done a study on any mesh

4 material, correct?

5 A. Correct.

6 Q. Never done a study on SUI in women,

7 correct?

8 A. Correct.

9 Q. Don't have any current research on

10 women's health, correct?

11 A. Correct.

12 Q. You're not an expert in chemical

13 engineering, correct?

14 A. Correct.

15 Q. Not an expert in pathology, correct?

16 A. Correct.

17 Q. You're not an expert in polymer

18 chemistry, correct?

19 A. Correct.

20 Q. You've got no background whatsoever in

21 polymer chemistry, correct?

22 A. Well, as far as dealing with the mesh

23 products, that would be the only background that I

24 would have.

1 Q. You have no educational background in
2 polymer chemistry whatsoever, correct?

3 A. Correct.

4 Q. Undergrad or medical education,
5 correct?

6 A. Correct.

7 Q. Whatsoever? Okay.

8 You've never done bench research on
9 synthetic mesh, correct?

10 A. Correct.

11 Q. Never done any lab research on
12 synthetic mesh, correct?

13 A. Correct.

14 Q. Never done any bench research on SUI
15 devices, period, correct?

16 A. Correct.

17 Q. Never done any lab research on SUI
18 devices, correct?

19 A. Correct.

20 Q. You are not a biomaterials specialist,
21 correct?

22 MR. MORIARTY: Objection. Form.

23 Go ahead.

24 THE WITNESS: Same thing I said earlier

1 about the polymer chemistry. With my, you know,
2 clinical experience in handling those type of
3 things, I'm very comfortable with it.

4 BY MR. JONES:

5 Q. You've never held yourself out as a
6 biomaterials specialist before, correct?

7 A. No.

8 Q. Okay. And you've never published
9 anything in the medical literature?

10 A. Correct. Well, no, wait. No. I take
11 that -- yes, I have published.

12 Q. I'll strike that.

13 A. I've got a couple --

14 Q. I'll strike that. That's a bad
15 question.

16 Let me get to -- how about this:

17 The -- any of the opinions that you're expressing
18 in your general expert report, have any of those
19 opinions been published in a peer-reviewed medical
20 journal?

21 A. Have any of my opinions? Specifically
22 my opinions?

23 Q. Yes.

24 A. No.

1 Q. Okay. And you've never tried to have
2 any opinions that you've expressed in your report
3 published in peer-reviewed medical literature,
4 correct?

5 A. Correct.

6 Q. And no one's asked you to ever try to
7 have your opinions published in any peer-reviewed
8 medical literature, correct?

9 A. Relating to SUI?

10 Q. Yeah.

11 A. Correct.

12 Q. You've never published anything,
13 medical literature or otherwise, on the appropriate
14 warnings that must be in medical device IFUs,
15 correct?

16 A. Correct.

17 Q. You've never studied what warnings are
18 required to be in a medical device IFU, correct?

19 A. Repeat that question.

20 Q. You've never done a study --

21 A. Okay. You kind of confused me when you
22 say "You never studied," because --

23 Q. I'll ask a better question.

24 A. Correct.

1 Q. You've never done a study on what
2 warnings are required to be in a medical device
3 IFU, correct?

4 A. Correct.

5 Q. You've never done a study on what
6 industry standards govern medical device IFUs,
7 correct?

8 A. Correct.

9 Q. You don't know what industry standards
10 govern medical device IFUs, correct?

11 A. I think I would say I know what -- what
12 standards govern it. The FDA has --

13 Q. Industry standards.

14 A. I guess --

15 Q. Industry standards. So the industry
16 among -- the standards among the industry. Putting
17 aside regulation standards, I'm just asking, are
18 you familiar with the industry standards that
19 govern what warnings must be in medical device
20 IFUs?

21 A. I guess I believe I do know what they
22 are. Again, it relates to, you know, specifically
23 the safety of the -- of the device; that is
24 important to me in IFUs. The potential

1 complications that can be -- can be related to the
2 device, specifically to the device.

3 Does that answer your question?

4 Q. Are those all the industry standards
5 you're familiar with that govern what warnings must
6 be in a medical device IFU?

7 A. I'm sure that there are more.

8 Q. As you sit here today, you can't think
9 of those, correct?

10 A. I can probably think about them for a
11 while and name some things, but I'd have to think.

12 Q. Tell you what, next break, I'll give
13 you all the time you want to think about it, and
14 just see what you can come up with tonight. If you
15 come up with any, just let us know at any time.

16 What -- since you're familiar with the
17 industry standards that govern the warnings on
18 medical devices, I have a series of questions for
19 you.

20 A. Okay.

21 Q. Is it true that a medical device
22 company must include all risks that are associated
23 with the device in the IFU?

24 A. No.

1 Q. Is it true a medical device company
2 must include all possible risks associated with the
3 use of the device in the IFU?

4 A. No.

5 Q. Do you agree that a medical device
6 company must include all risks associated with the
7 proper use of the device in the IFU?

8 A. No.

9 Q. Is it your opinion that the only risk a
10 medical device company must include in the IFU is a
11 risk associated with the unique use of that device?

12 A. That's correct.

13 Q. What is the risk that you believe
14 Ethicon must include in the TVT-O IFU?

15 A. I think that the -- the main risk is
16 exposure of the graft.

17 Q. Exposure of the mesh --

18 A. Mesh -- thank you --

19 Q. -- correct?

20 A. -- according to my definition.

21 Q. Exposure of the mesh.

22 Any other risk required under the
23 industry standards that Ethicon must include in the
24 IFU?

1 mesh company IFUs, you won't be using that
2 experience as background for your opinions as to
3 the adequacy of the Ethicon TVT IFUs?

4 A. No.

5 Q. The same question for any other medical
6 device IFUs that you've reviewed.

7 A. Which ones would you say?

8 Q. The da Vinci and robot ones.

9 A. No, I wouldn't use the IFU for that.

10 Q. Okay. Any other AMS mesh IFUs?

11 A. No. I haven't used any other AMS mesh
12 products.

13 Q. Okay. As you sit here today, can you
14 point to a single medical device IFU that you've
15 used in all your time as a urologist that adheres
16 to your standard of only risk -- only listing the
17 risk that is associated -- uniquely associated with
18 that device?

19 A. None of them do.

20 Q. None of them do?

21 A. No.

22 Q. Not a single medical device IFU that
23 you've ever looked at in your time as a urologist
24 adheres to the standard that you've presented

1 today, correct?

2 A. Correct.

3 Q. Are you familiar with the Abbott
4 article?

5 A. Spell that.

6 Q. A-b-b-o-t-t.

7 A. Abbott?

8 Q. Sarah Abbott?

9 A. Not off the top of my head, no.

10 Q. Mickey Krimm is a coauthor on it?

11 A. The names sound familiar, but I'm not
12 sure. I obviously can't tell you specifics.

13 Q. 2014?

14 A. I don't know. I don't know the
15 specifics. When I read my articles, I honestly
16 don't remember the authors.

17 Q. Okay. It discusses warnings -- warning
18 statements --

19 A. Okay.

20 Q. -- in IFUs.

21 A. Right.

22 Q. Still nothing?

23 A. Sounds familiar, vaguely familiar, but
24 I'm not sure.

1 correct?

2 A. No.

3 Q. Have you reviewed the design history
4 file for laser-cut mesh?

5 A. I've read some articles about the
6 laser-cut mesh, but I'm not certain exactly what
7 you're talking about --

8 Q. Okay. You --

9 A. -- but I've read documents about it.

10 Q. Do you know what a design history file
11 is?

12 A. I can -- I guess I can guess. I'm not
13 specifically aware of --

14 Q. Don't guess.

15 A. Okay.

16 Q. Do you know what a -- do you know what
17 the stage-gates are in a design process for a
18 medical device?

19 A. No.

20 Q. Did Ethicon ever add any warnings to
21 the TVT-O IFU since launch?

22 MR. MORIARTY: Objection. Go ahead.

23 THE WITNESS: I'm not aware that
24 they've added to the TVT-O.

1 BY MR. JONES:

2 Q. How about the TVT-R?

3 A. Not that I'm familiar with.

4 Q. Okay. You're not familiar with any
5 changes -- strike that.

6 You're not familiar with any additions
7 that Ethicon's made to the warning statements in
8 the TVT-O or TVT-R IFU, correct?

9 A. I'm not aware of them.

10 MR. MORIARTY: When it's convenient,
11 let's take five minutes.

12 MR. JONES: Let's take five minutes.
13 Let's take a break.

14 (Brief recess.)

15 BY MR. JONES:

16 Q. Doctor, after a short break, are you
17 ready to proceed?

18 A. Yes.

19 Q. Do you use the website
20 ceramsey@charter.net?

21 A. That's a -- may be an old email address
22 of mine.

23 Q. Okay. But you're familiar with that
24 email address?

1 Q. -- will you be offering any opinions in
2 this litigation that any of the TVT-O products are
3 safer than any of the TVT products? Meaning --
4 meaning, will you be making a distinction as to the
5 level of safety of those devices -- will you be
6 offering an opinion that TVT-R is safer than TVT-S?

7 MR. MORIARTY: Objection --

8 THE WITNESS: No.

9 MR. MORIARTY: -- form.

10 BY MR. JONES:

11 Q. Will you be offering an opinion in this
12 litigation that TVT-S is safer than TVT-R?

13 A. I would say yes.

14 Q. Okay. Will be you offering an opinion
15 in this case that TVT-S is safer than TVT-O?

16 A. Yes.

17 Q. Will be you offering an opinion that --
18 in this case that mini-slings are safer than
19 Retropubic slings?

20 A. Yes.

21 Q. Will be you offering an opinion in this
22 litigation that mini-slings are safer than
23 Obturator slings?

24 A. Yes.

1 Q. Exhibit 4 is your CV?

2 A. Okay.

3 Q. Correct?

4 A. Yes.

5 Q. Do you recognize this as your CV?

6 A. I do.

7 (Whereupon Exhibit 4 was marked as an
8 exhibit.)

9 THE WITNESS: Impressive.

10 BY MR. JONES:

11 Q. It is. A couple things --

12 A. It's not as long as the other ones I've
13 seen.

14 Q. Proctoring, you've listed proctor for
15 Ethicon and Intuitive Surgical, correct?

16

17 A. Correct.

18 Q. Those are both medical device
19 companies, correct?

20 A. Correct.

21 Q. Have you done any proctoring for --
22 outside of proctoring for medical device companies?

23 A. Proctoring for medical. . .

24 I'm sorry. I have to think about that.

1 A. No.

2 Q. Have you ever given any presentations
3 at any medical societies on transvaginal mesh?

4 A. No.

5 Q. Have you given any presentations to
6 medical societies on female stress urinary
7 incontinence?

8 A. No.

9 Q. Have you given any presentation at any
10 medical society since 2001?

11 A. No.

12 Q. And when did you finish your residency?

13 A. 2002.

14 Q. Okay. Following your residency, have
15 you given a single presentation at any medical
16 society?

17 A. No, not at a medical society, no.

18 Q. Okay. That obviously includes SUI,
19 female SUI --

20 A. Correct.

21 Q. -- transvaginal mesh? Yeah.

22 Under "Research" you've listed two
23 entries --

24 A. I have.

1 Q. -- one in '96 and one in '94.

2 Have you done any research since the
3 entry listed March 1996?

4 A. Not what I would call clinical
5 research.

6 Q. Not that you would list here on your
7 CV?

8 A. Right. Not -- the presentations were
9 research, but. . .

10 Q. Okay. Under "Medical Societies,"
11 when -- are you a member of AUGS?

12 A. No.

13 Q. Are you a member of SUFU?

14 A. No.

15 Q. Are you a member of ICS?

16 A. No.

17 Q. IUGA?

18 A. No.

19 Q. AGOS?

20 A. No.

21 MR. MORIARTY: He's making them up now.

22 BY MR. JONES:

23 Q. Have -- are you a urogynecologist?

24 A. No.

1 Q. Did you do a fellowship?

2 A. No.

3 Q. Okay. Did you apply to sit for the
4 FPRM exam in 2013?

5 A. You're making that one up, too.

6 Q. Yeah. I may be.

7 A. No. No. I know what you're talking
8 about. No, I did not.

9 Q. Okay. If you know the proper acronym,
10 feel free to correct me.

11 Female Pelvic -- but you understand
12 that there was a credentialing program sometime in
13 2003 -- 2013?

14 A. Yes.

15 Q. And you didn't apply to take that test?

16 A. No.

17 Q. Why not?

18 A. Because I didn't do most of the things
19 that they do, which is a lot of pelvic floor. . .

20 Q. Okay. So you wouldn't have even
21 qualified to take the test, correct?

22 A. Probably could have -- sure, I could
23 have qualified to take the test. I don't think
24 that they had any -- anybody can take the test if

1 you're a urologist or a gynecologist, but I
2 wouldn't -- I wouldn't have done it.

3 Q. If you had researched it and there was
4 a minimal requirement for the level of -- or level
5 and/or number of pelvic floor surgeries that you
6 had to do in order to even sit for the exam, it's
7 possible that you wouldn't have been even able to
8 sit for the exam, correct?

9 A. That's true.

10 Q. Okay. And you're not -- as you sit
11 here today, you don't know the requirements,
12 correct?

13 A. No.

14 Q. But you didn't try to apply for it?

15 A. No.

16 MR. MORIARTY: So it's after 9:00.
17 Let's just look for the next convenient stopping
18 point.

19 MR. JONES: Okay.

20 BY MR. JONES:

21 Q. Under "Honors," "Leadership,"
22 "Publications," "Presentations," and/or "Research,"
23 none of the listings in your CVA [verbatim] relate
24 to SUI or transvaginal mesh, correct?

1 A. In my CV? No. Correct.

2 (Whereupon Exhibit 5 was marked as an
3 exhibit.)

4 BY MR. JONES:

5 Q. Exhibit 5.

6 A. I did bring them.

7 Q. You did bring them. Somebody brought
8 them.

9 What is Exhibit 5, Doctor?

10 A. When?

11 Q. What is Exhibit 5, Doctor?

12 A. What is -- oh, it's a consulting
13 agreement for Ethicon.

14 Q. Take a look -- take a second and look
15 through Exhibit 5, and all I'm going to ask is what
16 the documents are, if you're familiar with them,
17 you know, if your name appears on them and what
18 year they are. I'm just going to ask basic
19 questions like that --

20 A. Okay.

21 Q. -- and then we'll be done for the
22 evening. But take a second and look through them.

23 A. (Reviews documents.)

24 Okay. I've looked at the first one.

1 IN THE UNITED STATES DISTRICT COURT
 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
2 CHARLESTON DIVISION

IN RE: ETHICON, INC.) Master File No.
4 PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY)
5 LITIGATION) MDL No. 2327

6)
THIS DOCUMENT RELATES TO) JOSEPH R.
7 PLAINTIFFS:) GOODWIN
) U.S. DISTRICT
8 Mary Hendrix) JUDGE

	Case No. 2:12-cv-00595)
9	Danni Laffoon)
	Case No. 2:12-cv-00485)
10	Alfreda Lee)
	Case No. 2:12-cv-01013)
11	Mary Holzerland)
	Case No. 2:12-cv-00875)
12	Heather Long)
	Case No. 2:12-cv-01275)
13	Donna Shepherd)
	Case No. 2:12-cv-00967)
14	Cheryl Lankston)
	Case No. 2:12-cv-00755)

15 _____

16

17

18 CONTINUED
19 DEPOSITION OF

20 CHRISTOPHER E. RAMSEY, M.D.
21 Taken on behalf of the Plaintiff
22 April 7, 2016

23

24

Christopher E. Ramsey, M.D.

1 correct?

2 A. Yes.

3 Q. 2014, you performed work for Ethicon,

4 correct?

5 A. Yes.

6 Q. Same for 2013?

7 A. Probably not.

8 Q. Probably not. So we've got from 2003

9 to 2012 you were a consultant for Ethicon, correct?

10 A. Correct.

11 Q. A paid consultant for Ethicon from 2002

12 to -- from 2003 to 2012, correct? I'll restate

13 that.

14 From 2003 to 2012, you were a paid

15 consultant for Ethicon, correct?

16 A. Between those years, I was.

17 Q. Okay. And then, starting back up in

18 2013, you once again renewed your relationship with

19 Ethicon as a consultant physician, correct?

20 MR. MORIARTY: Objection. Asked and

21 answered.

22 THE WITNESS: 2014.

23 BY MR. JONES:

24 Q. 2014. So following becoming board

Christopher E. Ramsey, M.D.

1 MR. MORIARTY: Objection. Form.

2 THE WITNESS: I don't think that they
3 bring into question the safety. They bring into
4 question the efficacy.

5 BY MR. JONES:

6 Q. You know that the FDA's position on
7 TVT-Secur is that the efficacy of TVT-Secur has not
8 been adequately demonstrated, correct?

9 A. I don't think that they're saying that
10 it has not been adequately demonstrated. I think
11 they're saying that they would like to see more
12 information to show that it has efficacy.

13 Q. Do you agree or disagree that the FDA's
14 current position is that the safety of the
15 TVT-Secur device has not been adequately
16 demonstrated?

17 MR. MORIARTY: Objection.

18 THE WITNESS: I don't think that's
19 their position.

20 BY MR. JONES:

21 Q. Do you agree or disagree that the FDA's
22 position is that the efficacy of the TVT-Secur
23 device has not been adequately demonstrated?

24 A. Again, I think that they have concerns

Christopher E. Ramsey, M.D.

1 directors at Ethicon as to the adequacy of the
2 warnings in the TVT IFUs?

3 A. I think that the IFUs are adequate, and
4 so I -- I -- I think that anything that's been
5 discussed inside of Ethicon doesn't really pertain
6 to what would apply to me.

7 Q. The discussions Ethicon medical
8 directors had inside the company about the warnings
9 in the TVT IFUs are not relevant to you, correct?

10 A. I think they need to have these
11 discussions and be very candid within themselves
12 about what needs to be put in an IFU before they
13 put it in the IFU.

14 So once it is in the IFU -- and I've
15 looked at the IFU and I think the IFU is
16 adequate -- whatever went on within Ethicon doesn't
17 pertain to me. I mean, that's all internal
18 business decisions that don't apply to me
19 clinically.

20 Q. Do you think Ethicon makes business
21 decisions on what to include in its TVT IFUs?

22 A. I don't think they make business
23 decisions to include what goes in the IFU.

24 Q. How many times has Ethicon changed the

1 TVT-Secur IFU?

2 A. The TVT-Secur IFU?

3 Q. Yeah.

4 A. Honestly, I don't know how many times
5 they've changed the TVT-Secur IFU.

6 MR. JONES: I'll mark for the record
7 Exhibit 15.

8 (Whereupon Exhibit 15 was marked as an
9 exhibit.)

10 BY MR. JONES:

11 Q. Take a look at Exhibit 15, Doctor.

12 A. Okay.

13 Q. Turn -- what is Exhibit 5?

14 A. It says "Gynecare TVT" Tension-Free
15 Vaginal Tape, 2015.

16 Q. Okay. Do you recognize --

17 A. It's instructions for use.

18 Q. You recognize Exhibit 15 as the
19 Gynecare TVT instructions for use, correct?

20 A. For TVT.

21 Q. For TVT Retropubic, correct?

22 A. Does it say "retropubic"? It just says
23 "TVT vaginal tape."

24 Q. You recognize Exhibit 15 as the

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1 list the frequency of the adverse reactions in the
2 IFU?

3 A. No.

4 Q. Should a medical device company list
5 the frequency of the adverse reactions in the IFU?

6 A. No.

7 Q. Should a medical company list the
8 severity of the adverse reactions in the IFU?

9 A. No.

10 Q. Should a medical company list the
11 duration of the adverse reactions listed in the TVT
12 IFU?

13 A. Not in the IFU, no.

14 Q. Should a medical device company make
15 any statements about the duration of adverse
16 reactions in the IFU?

17 A. No.

18 Q. Should Ethicon make any statements
19 about the specific design features unique to the
20 TVT mesh in the IFU?

21 MR. MORIARTY: Objection. Form.

22 Go ahead.

23 THE WITNESS: The specific design
24 features on how to use it, yes.

1 A. I don't think it is.

2 Q. Okay. Mesh -- the mesh used in the TVT
3 line of products in your opinion can never be a
4 cause of chronic pain in women, correct?

5 A. I don't believe the mesh is the cause
6 of chronic pain in women.

7 Q. And the mesh used in the TVT line of
8 products in your opinion can never be the cause of
9 chronic pain in women, correct?

10 A. It's not the cause of chronic pain.

11 Q. Okay. The mesh used in the TVT line of
12 products in your opinion cannot be a cause of
13 dyspareunia, correct?

14 A. I don't think that the mesh is a cause
15 of dyspareunia.

16 Q. Never, correct?

17 A. I've never seen it.

18 Q. Ever?

19 A. I have not, not in my clinical
20 practice.

21 Q. You've never read about it either, have
22 you?

23 A. I've read about it in certain articles
24 that suggest it, but I don't -- I don't think

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1 that's the case.

2 Q. Okay. You've read in medical journal
3 articles that the mesh used in the TVT line of
4 products can be a cause of dyspareunia, correct?

5 A. In some articles they suggest that it
6 can be.

7 Q. You disagreed with those articles,
8 correct?

9 A. Yes.

10 Q. Okay. And can the mesh used in the TVT
11 line of products be a cause of discomfort for
12 women?

13 A. Yes, it can be.

14 Q. Okay. Can the mesh used in the TVT
15 line of products cause irritation to women's
16 vaginal tissues?

17 A. With an exposure, there can be some
18 irritation.

19 Q. When the mesh used in the TVT line of
20 products is exposed, it can cause irritation to
21 women, correct?

22 A. Correct.

23 Q. It can cause discomfort to women,
24 correct?

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1 Q. And did you follow that?

2 A. Yes.

3 Q. And is that something that you followed
4 throughout the term of your consulting --

5 A. Yes.

6 Q. -- relationship with Ethicon?

7 A. Yes.

8 Q. Did you know that internally Ethicon
9 considered TVT-Secur a failed product?

10 MR. MORIARTY: Objection. Form.

11 Go ahead.

12 THE WITNESS: I didn't know that.

13 BY MR. JONES:

14 Q. You've never seen any document where
15 Ethicon employees referred to TVT-Secur as a failed
16 product?

17 A. No.

18 Q. You've never seen any internal
19 documents where the engineers who worked on the
20 design of TVT-Secur referred to it as a failed
21 product?

22 A. No.

23 Q. Have you seen any presentations by
24 Ethicon related to TVT-Secur discussing the lessons

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1 BY MR. JONES:

2 Q. I've marked Exhibit 9 [verbatim], which
3 is a printout from Tennessee Urology Associates'
4 website.

5 Do you recognize this?

6 A. Yes.

7 Q. Is this your website?

8 A. It looks like it. It's brand new.

9 Q. Okay. And under -- at the bottom of
10 page 1, under "Da Vinci Surgery Providers," there's
11 a paragraph explaining background information about
12 yourself, correct?

13 A. Right.

14 Q. It reads, "Dr. Ramsey's practice has a
15 special concentration in robot-assisted
16 laparoscopic procedures," correct?

17 A. Yes.

18 Q. And does it state anywhere on this
19 website that you have a special concentration in
20 treatment of female SUI?

21 A. Well, this is the da Vinci surgery page
22 on our -- on our website. And under a bio of
23 myself, there should be -- and if there's not, I
24 need to correct it because this is -- it's a

1 relatively -- we have a new website that we have
2 through our company.

3 Our old website had all the procedures
4 we used to use, and this is new. So I haven't
5 looked at it since this has been done. But it
6 should say all the things that I provide, including
7 stone surgery, treatment of the cancers --

8 Q. Okay.

9 A. -- erectile dysfunction, stress
10 incontinence.

11 So -- but this is a specific link on
12 that. This isn't just my page; this is a -- the
13 da Vinci page for patients who are interested in
14 that part.

15 Q. Okay. Your website profile is listed
16 in the da Vinci surgery website on Tennessee
17 Urology Associates, correct?

18 A. Say that one more time.

19 Q. Your profile is listed on the da Vinci
20 surgery website on Tennessee Urology Associates,
21 correct?

22 A. I guess I don't know what you mean by
23 "the da Vinci surgery website."

24 Q. The da Vinci section.

1 A. The section, yes.

2 MS. MEAD: Madam Court Reporter?

3 (Off-the-record discussion.)

4 BY MR. JONES:

5 Q. So at least according to this exhibit,
6 nowhere do you list any special concentration or
7 emphasis --

8 (Off-the-record discussion.)

9 BY MR. JONES:

10 Q. All right. Doctor, let's proceed.

11 According to Exhibit 29, which is a
12 section of the Tennessee Urology Associates
13 website, you don't list any special concentration
14 in treating female SUI, correct?

15 A. It wouldn't be on that page.

16 Q. Okay. If -- if it is on the website, I
17 can go there and pull it; we'll find it, right?

18 A. If it is on there, yeah.

19 Q. Okay.

20 A. And if it it's not, I want to know so I
21 can get it updated --

22 Q. That's fine.

23 A. -- so thanks for checking.

24 (Whereupon Exhibit 30 was marked as an

1 exhibit.)

2 BY MR. JONES:

3 Q. Let's look at Exhibit 30. Tell me what
4 Exhibit 30 is.

5 A. It's a Tennova Hospital. It's one of
6 the local hospital chains.

7 MR. MORIARTY: Do I get one?

8 MR. JONES: Yeah.

9 BY MR. JONES:

10 Q. Do you practice there?

11 A. That's where I do some of my surgeries.

12 Q. Okay. Anywhere on this website does it
13 state you have a special concentration in treating
14 female SUI?

15 A. It does not.

16 Q. Okay. It does state you have a special
17 concentration in robotic-assisted -- robotic-
18 assisted laparoscopic surgery, though, correct?

19 A. Yes.

20 Q. You can put that aside.

21 (Whereupon Exhibit 31 was marked as an
22 exhibit.)

23 BY MR. JONES:

24 Q. Do you believe that in -- serving as a

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1 so --

2 Q. Okay. I'll strike that question.

3 Withdraw that question. Won't use that one.

4 Never attended any of the annual

5 Ethicon summits, outside of the one time you

6 visited New Jersey, correct?

7 A. Not that I remember.

8 Q. Okay. Not that you remember, so it's

9 possible?

10 A. I didn't.

11 Q. Okay. You didn't?

12 A. (Witness moves head up and down.)

13 Q. Last couple questions. Are you

14 familiar with the article "TVT-Secur single-

15 incision sling after 5 years of follow-up: The

16 promises made and the promises broken"?

17 A. I may have read that. I'm not

18 certain --

19 Q. Sort of a significant title, "promises

20 made and promises broken."

21 A. Who wrote it?

22 Q. Francois Haab.

23 A. Haab. I'm not familiar with that,

24 but --

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1 Q. Okay.

2 A. -- I'm not -- I'm not very familiar
3 with the article. I may have read it.

4 Q. If it's not on your reliance list,
5 you're not relying on it, correct?

6 A. If it's not on my reliance list, I
7 probably did not read it.

8 Q. Okay. But a title like that, promises
9 made and promises broken with TVT-Secur, would be
10 kind of -- sticks out, correct?

11 A. Sure. What journal was that in? Does
12 it say?

13 Q. "Urology."

14 A. Okay.

15 Q. 2012.

16 A. Okay.

17 Q. Not familiar with it?

18 A. Not off the top of my head.

19 Q. Not on your reliance list?

20 A. I don't know.

21 Q. Feel free, if you want to take -- go
22 off the record and look at your reliance list and
23 see if it's on there.

24 THE WITNESS: Do you have my reliance

1 list?

2 MR. MORIARTY: Have you already looked?

3 MR. JONES: It's not on there.

4 THE WITNESS: Okay. It would take me a
5 while to look through it.

6 BY MR. JONES:

7 Q. So if you'll -- you can look at another
8 time, but based on the representation that it's not
9 in your reliance list, it's an article that you
10 won't be relying on, correct?

11 A. Correct.

12 Q. Okay. And you're not familiar with it,
13 correct?

14 A. No, I don't remember the article.

15 Q. Okay. Have you read any TVT-Secur
16 articles by Dr. Newman?

17 A. Newman? Not that I know of.

18 Q. Okay. Have you seen any -- has Ethicon
19 shown you any internal memos or communications from
20 Dr. Newman about the TVT-Secur device?

21 A. I wouldn't know.

22 Q. None that stand out as you sit here
23 today?

24 A. I don't recollect Dr. Newman.